

Serial No. 09/160,618

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(b) orally administering the dosage form to the mammal, wherein the carrier has a A_w of about 0.60 to about 0.75, a soft and chewy texture, and A_w is variable dependent on the properties of the pharmaceutical additive.

28. The carrier of claim 12, wherein the temperature of the carrier during its preparation the extrusion process is maintained at a temperature below that which would degrade the additive.--

REMARKS

In the above identified Office Action the Examiner has indicated that claims 1-25 were examined. The Examiner has objected to claims 1-11 and 24 as polyhydric was misspelled in amended claim 1. By the above amendments this matter has been corrected and as such, the claims are now considered to be acceptable.

The Examiner has also rejected the claims as being unpatentable over the patent to Borkan. The Examiner has stated that Borkan teaches a chewable soft gelatin capsule and has interpreted the term "carrier" as pertaining to the capsule shell of Borkan. Applicant has amended the claims so that it now claims an extrudate including a matrix. Borkan is not an extrudate, but rather is a gelatin capsule having filling material within. Such is not an extrudate and obtains its softness and chewiness in different manners. The Examiner has stated that saccharin could be substituted with sugar, however it is noted that Borkan teaches that the saccharine is to be added to the solvent base of the present capsule and not to the gelatin skin itself. As such, the saccharin is there for flavoring purposes and not for softening purposes or lowering the water activity as is the

Serial No. 09/160,618

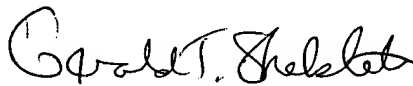
function of sugar in Applicant's invention. Therefore, there can be no teaching or suggestion in Borkan to add sugar to the extrudate carrier to lower the water activity and thus contribute to a soft and chewy texture.

The claims have also been rejected as unpatentable over Borkan, in view of Seth. The Examiner is using Seth for the teaching of a starch that is a well know thickener in the contents of pharmaceutical capsules. However, Seth does not cure the deficiency in Borkan noted above, i.e. that the subject invention involves an extrudate, something not taught or suggested by either Borkan or Seth, and thus the rejection cannot stand.

With the above amendments this application is considered ready for allowance. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below-listed number.

Respectfully submitted,

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By 

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